

## **II. REMARKS**

Claims 1-8, 21, 22, 24-29, 34-36, 49, 56, 58, ~~62~~<sup>60</sup>, 64, and 68-82 are pending and stand variously rejected under 35 U.S.C. §§ 112 and 103. Claims 60 and 83-86 have been withdrawn from consideration by the Examiner. Claim 62 was previously canceled without prejudice or disclaimer.

Claims 1 and 21 have been amended herein to make explicit that the *lux* and *luc* sequences encode luciferase gene products. In addition, claim 1 has also been amended to incorporate the limitations of previous claim 68. Accordingly, claim 68 has been canceled, without prejudice or disclaimer. Claims 28 and 69 have been amended to correct dependency. Claims 79-82 have been amended to indicate the methods involve providing "a" substrate, as described, for example, on page 23, line 26 and 32, lines 10-16, particularly, line 12. Thus, claims 1-8, 21, 22, 24-29, 34-36, 49, 56, 58, 64, and 69-82 are pending.

The foregoing amendments are not intended to be an acquiescence in the Office's assessment of those claims in the February 11, 2003 Office action, and Applicants expressly reserve the right to bring the subject matter of the original claims again in a subsequent, related application. Further, upon allowance of generic claims, Applicants request consideration of claims to additional species that are written in dependent form or which otherwise include all the limitations of the allowed generic claims (for example, claims 60 and 83-86).

### **Claim Objections**

The Examiner has objected to claims 1 and 21 for use of abbreviations "lux" and "luc." (Office Action, page 2). Claim 28 is objected to for allegedly improper dependency.

Without conceding the correctness of the Examiner's position and solely to expedite prosecution, the term "luciferase" has been inserted into these claims to explicitly recite what one of skill in the art would have readily understood from the use of the terms *lux* and *luc* in the original claims.

With regard to claim 28, Applicants thank the Examiner for the suggested change in dependency and have incorporated the suggestion by amendment herein. The same change has been made to claim 69.

In view of the foregoing, the objections to claims 1, 21 and 28 have been obviated.

### **35 U.S.C. § 112, First Paragraph, Written Description**

Claims 79-82 stand rejected as allegedly containing "new matter" by reciting "one or more substrates." (Office Action, page 3). In addition, claims 1-3, 5-8, 21, 22, 24-28, 34-36, 49, 56, 64 and 68-82 stand rejected as allegedly not described in sufficient structural or functional

detail. (Office Action, pages 4-5). Applicants traverse the rejections and supporting remarks and address each rejection in turn.

### **New Matter**

Applicants submit that no new matter was added by reciting "one or more substrates" in claims 79-82. The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See, e.g., *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981) and MPEP § 2163.06. In the pending case, the alleged "added" information did not in any way go beyond the subject matter originally filed. In this regard, Applicants direct the Examiner's attention to page 23, line 26 and page 32, line 12, where various substrates of luciferase are disclosed. In view of this clear description of "one or more" possible substrates for luciferase, Applicants respectfully request that this rejection was improper and should have been withdrawn.

Nonetheless, solely to expedite prosecution, the objectionable language has been removed by amendment herein. In particular, Applicants have replaced the language "one or more" with the equivalent term "a." (See, *PPG Indus v. Guardian Indus Corp.* 48 USPQ2d 1351, 1353 (Fed. Cir. 1998); *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 52 USPQ2d 1109, 1112, 1353 (Fed. Cir. 1999); *AbTox, Inc. v. Exitron Corp.*, 43 USPQ2d 1545, 1548 (Fed. Cir. 1997); Robert Faber ed., *Landis on Claim Drafting* 531 (3 ed. 1990) establishing that the term "a" in patent parlance carries the meaning of "one or more" in open-ended claims containing the transitional phrase "comprising").

Therefore, the new matter rejection was improper and, in any event, has been obviated by the foregoing amendments.

### **Written Description**

Turning now to the rejection of claims 1-3, 5-8, 21, 22, 24-28, 34-36, 49, 56, 64 and 68-82 as allegedly not adequately described in the specification as filed, Applicants note the following.

The written description requirement is highly fact-dependent and there is a strong presumption that an adequate written description of the claimed invention is present at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim*, 191 USPQ 90 (CCPA 1976). The first step in a written description inquiry is to properly construe the claims as issue:

Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. [citation omitted] The entire claim must be considered, including the preamble and the transitional phrase. The claims as a whole, including all the limitations found in the preamble, the transitional phrase, and the body of the claims, must be sufficiently supported to satisfy the written description requirement. (66 Fed. Reg. 1099, 1105).

Only after the claims are properly constructed, can an analysis of the adequacy of the description begin. Furthermore, the written description requirement of section 112 does not require that the claims be limited in scope to particular sequences (*e.g.*, particular sequences encoding luciferases). Indeed, the courts have consistently found that DNA may be properly defined by one or more of the following parameters: "structure, formula, chemical name or physical properties." *Fiers v. Revel*, 25 USPQ2d 1601 (Fed. Cir. 1993). The recent PTO guidelines on written description are equally clear that particular sequences are not required to satisfy 35 U.S.C. § 112, first paragraph:

[t]he description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is a product or a process. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics. (Final Examiner Guidelines on Written Description, 66 Fed. Reg. 1099, emphasis added).

Simply put, there is absolutely no requirement that Applicants disclose particular sequences making up the claimed polynucleotides. Rather, the test is whether the specification reasonably conveys possession of the invention in view of a thorough reading of the disclosure and the knowledge possessed by the skilled artisan at the time of filing, for example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lukach*, 169 USPQ 795, 796 (CCPA 1971). *In re Lange*, 209 USPQ 288 (CCPA 1981).

Applying these rules to the instant application, Applicants submit that the specification more than adequately describes the subject matter of pending claims 1-3, 5-8, 21, 22, 24-28, 34-36, 49, 56, 58, 64 and 68-82.

First and foremost, claims 1-3, 5-8, 34-26, 49, 56, 58 and 64 do not, as asserted by the Office, encompass "naturally occurring [lux operons] in any prokaryote wherein the lux operon

has any order of the genes and is man made or mutated.” (Office Action, page 4). Rather, when properly construed, it is clear that all these claims require that the lux operons be arranged with additional elements and in a particular structure that is not naturally occurring. The specification more than adequately describes both relevant, identifying structural (e.g., the order of the lux operons, the position of the gram-positive ribosome binding sites) and functional (e.g., encodes luciferase, transcription results in polycistronic RNA) characteristics of the expression vectors and methods of using these expression vectors as set forth in pending claims 1-3, 5-8, 34-26, 49, 56, 58 and 64.

Similarly, claims 21, 22, 24-28 and 69-82 are all drawn to compositions and methods that include a non-naturally occurring expression cassettes structured to include luxA, luxB and luc-encoding sequences as well as Gram-positive ribosome-binding site sequences. The claims also specify the location of the ribosome-binding site sequences relative to the luciferase coding sequences and specify that each of the luxA, luxB, and luc gene products is expressed as an individual polypeptide. The actual sequences of various luxA, luxB and luc-encoding sequences were well known. What was not known prior to Applicants’ disclosure is that these sequences could be structured and organized in expression cassettes and shuttle vectors as claimed. It is evident that the specification more than adequately describes how to select known lux and luc sequences and how to organize these sequences with additional polynucleotides into the claimed expression cassettes. Therefore, the specification adequately describes sufficient, relevant structural and functional features of these expression cassettes.

In sum, ample structure (e.g., organization, order, components) and identifying characteristics of the claimed compositions and methods are provided so that a skilled artisan would recognize that Applicants were in possession of the claimed invention at the time of filing. As such, the written description requirement is satisfied and Applicants respectfully request that this rejection be withdrawn.

### 35 U.S.C. § 112, Second Paragraph

Claims 6-8, 25-27, 35 and 71 stand rejected as allegedly indefinite. (Office Action, page 5). In particular, the metes and bounds of the abbreviations recited in claims 6-8 and 25-27 are allegedly not found in the specification as filed. (Office Action, page 6). Similarly, the metes and bounds of the term “mini-transposon” as recited in claims 35 and 71 are alleged not be defined in the specification as filed. (Office Action, page 6).

Applicants traverse the rejections and supporting remarks.

It is axiomatic that definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular disclosure at issue, (2) the teachings of the art, and (3) the interpretation that would be given by one possessing and ordinary level of skill in the

pertinent art the time the invention was made. *See, e.g., In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). Consequently, a claim that is understandable to one skill in the art meets the requirements of the second paragraph of 35 U.S.C. § 112.

With this legal framework in mind, Applicants note the following. The designations Sa1-6 and Sp1-17 in claims 6-8 and 25-27 are not abbreviations, as asserted by the Office. (Office Action, page 6). Instead, these designations clearly refer to expression enhancing sequences (EES) identified as set forth in Example 4B (page 38) and Example 8C (page 47). Therefore, a skilled artisan reading the specification would readily be apprised of the fact that the designations Sa1 through Sa6 refer to EES derived from *S. aureus* (see, page 38, lines 25-27) while the designations Sp1, Sp5, Sp6, Sp9, Sp16 and Sp17 refer to EES derived from *S. pneumoniae* (see, page 46, lines 3-5). Thus, the metes and bounds of claims 6-8 and 25-27 are more than clear when properly viewed in light of the disclosure.

Likewise, one of skill in the art would readily understand the metes and bounds of the term "mini-transposon" as recited in claims 35 and 71. Indeed, it is clear from specification that mini-transposons are modified forms of transposons and may be suitable for delivering expression vectors. (See, page 5, lines 5-10). Furthermore, the term "mini-transposon" was well-known in the art as of Applicants' priority date to refer to transposons containing less than all sequences of a full-length transposon but which still function to insert sequences into a host cell. A search of Medline revealed over 30 publications describing mini-transposons as of the date of filing and selected abstracts of this search are attached hereto.

In brief, Applicants note that claims 6-8, 25-27, 35 and 71 are sufficiently clear when read in light of the specification and state of the field. Accordingly, Applicants request that the rejection be withdrawn.

### Rejections Under 35 U.S.C. §103

The Examiner rejected claims 1-8, 49, 58, 64 and 75 stand rejected as allegedly obvious over Meighen in view of Vellanoweth. (Office Action, page 7). In addition, claims 34 and 35 stand rejected as allegedly obvious over Meighen in view of Vellanoweth and further in view of Legocki. (Office Action, page 8). Finally, claim 36 stands rejected as allegedly obvious over Meighen in view of Vellanoweth and further in view of Sherf. (Office Action, page 9).

Applicants traverse for the reasons of record. Furthermore, in view of the foregoing amendments incorporating the limitations of claim 68 into claim 1 (and, accordingly, into dependent claims 2-7, 49, 58, 64 and 75), Applicants submit that the rejections have been rendered moot. In particular, there is no combination of the cited references that teaches or suggests a polynucleotide containing in relative order luxABCDE operons. Thus, Applicants respectfully request that the rejections be withdrawn.


**III. CONCLUSION**

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. § 112 and define an invention that is patentable over the art. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

If the Examiner notes any matters that may be facilitated by a telephone interview, Applicants request that the Examiner contact the undersigned at the telephone number given below.

Respectfully submitted,

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By:   
Dahna S. Pasternak  
Registration No. 41,411  
Attorney for Applicants

Cooley Godward LLP  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306  
Tel.: (650) 843-5608  
Fax: (650) 857-0663

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